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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,056	08/15/2005	Peter Frost	C70512	3967
20462 7590 04/29/2010 GlaxoSmithKline GLOBAL PATENTS -US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				
EXAMINER MAEWALL, SNIGDEHA				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
04/29/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

### Office Action Summary

**Application No.**

10/522,056

**Applicant(s)**

FROST, PETER

**Examiner**

Snigdha Maewall

**Art Unit**

1612

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1.5, 8-10 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1.5, 8-10 and 12-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-06)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 01/24/10

## **DETAILED ACTION**

### **Summary**

1. Receipt of IDS filed on 01/24/10 is acknowledged.

The information disclosure statement filed 01/24/10 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

The information disclosure statement filed 01/24/10 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

As such only USP 4,594,242 and EP-0319884-A1 have been considered in IDS filed on 01/24/10.

Amendment to specification filed on 01/24/10 has also been acknowledged.

The rejections not reiterated herein from the previous office action have been withdrawn in light of applicant's amendments to claims.

Claims 1 and 16 have been amended.

Claims **2-4, 6-7 and 11** have been cancelled.

New claim **19** has been added.

Claims **1, 5, 8-10 and 12-19** are under prosecution.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claim **1, 5, 8-10 and 12-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over WO0162211. ('211) (See Machine translation and translation attached and German patent DE 100 08 836A1 for translation purposes of WO 0162211, all presented in IDS and of record) in view of Stoltz (USP 5,824,289).

'211 discloses a propellant containing tooth cleaning agent, see title. The reference discloses tooth cleaning agents that contain polishing agents, humectants and tensides with celluloses that are filled in valve-operated dispenser filled with propellants, see abstract. The reference discloses stable dispersion which does not separate, see page 1, and paragraph 6. The amount of water is from 1-60 GEW by percent, see page 1, and paragraph 8. Various propulsion gas mixtures are provided

on page 2, paragraph 1 such as isopentane, neopentane and isobutene and mixture of C4 alkane and C5 alkane etc. (also see page 3 of German translation)

Polishing agents, finery bodies or abrasives which remove the tartar are disclosed on page 2, last paragraph. The polishing agents are finely divided with grain sizes and the amounts are disclosed to be between 5-50 GEW %. Suitable metaphosphates, calcium carbonates, and calcium phosphatase and various polishing agents are disclosed on page 2, 2-3 paragraph. Various silicas and silicates, alkali silicate and Zeodent are disclosed on page 2. Wet retaining means such as glycerol, propylene glycol and sorbitol are disclosed on page 2, section 5. Various surfactants are disclosed on page 2, section 6. The proportion of water in the composition is from, 1 to 60% by weight to 30 to 50% by weight and pH is from 5.5 to 9, see page 2 of translation. The preferred amount of propellant is from 3-4%, see under propellant gas in translation provided on page 2. On page 9 of translation the reference teaches binding agents and thickening agents. On page 4 of translation the mean particle size of polishing agents have been disclosed to be from 1 to 50 microns, 1 to 10 microns and from 1 to 200 microns and the amount of polishing agent is from 5 to 50% by weight. Humectants and surfactants are disclosed on page 6 of translation.

While the reference teaches utilizing propellants such as C4 alkane and isopentane etc., the reference does not specifically teach utilizing propellant mixture such as dimethylether and n-butane.

Stoltz teaches a foamable dental composition containing fluoride and aerosol propellant which provides stability to foam, see abstract and column 6, lines 61-67. The

reference teaches well known propellant such as n-butane, propane and dimethylether with various psig vapor pressures. The reference also teaches chlorodifluoromethane propellants, see column 8, lines 45-50. The reference teaches in column 7, lines 32-37 that persons of ordinary skill would realize using other propellants in combination with the disclosed ones that is n-butane and isobutene. Example in column 7 teaches using dimethylether.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to utilize the propellants such as n-butane and dimethylether in the primary reference in order to provide better dental foam stability motivated by the teachings of secondary reference. Optimization of various amounts of various ingredients would have been within the purview of skilled artisan at the time of instant invention absent evidence to contrary. Utilization of known propellants in the known aerosol dentifrice would have been obvious to one of ordinary skill in the art with an expectation to obtain predictable results that is a stable dental preparation.

#### **Applicants Arguments**

Applicant's arguments filed 01/24/10 have been fully considered but they are not persuasive.

Applicant argues that when only one propellant was used in the composition, the results were outside the stability parameters. Stoltz relates to oil in water emulsion which is a very different formulation and the Stoltz reference deals with addressing different problems dealing with fluoride foams. DME has not been disclosed in any of

the examples, the only mixture disclosed is isobutene and propane and all of this is taught in context with dispensing oil in water emulsion formulation with acidic pH range which is different from the claimed invention.

In response to applicants arguments that Stoltz deals with fluoride foams and oil in water emulsions, it is respectfully pointed out that the open ended comprising language does not exclude reading any other embodiments present in claims. The examples and preferred embodiments do not constitute teaching away. Additionally, Stoltz while teaching inclusion of propellant such as n-butane also teaches dimethylether in the example. The reference teaches in column 7, lines 32-40 that the foregoing propellants such as n-butane, isobutene have been set forth for purposes of illustration and not exclusion, persons skilled in the art will recognize that other aerosol propellants alone or in combination with others can also be use. Therefore utilization of mixture of n-butane and dimethylether would have been envisaged by one of ordinary skill in the art in light of the state of the art discussed above. Regarding unexpected results that by utilizing only n-butane or dimethylether propellant the parameters for stable and controllable foam were outside the range is really not unexpected because the prior art suggests utilizing one or more of propellants claimed. Further more, Stoltz explicitly teaches that foamable dental composition comprising propellant provides stability. Since the reference teaches that the dental foam is stable and suggests combination of n-butane and other propellants such as dimethylether in the dental composition, the claimed invention would have been obvious to one of ordinary skill in the art and one of ordinary would have prepared a stable composition with the two

specific propellants claimed. In response to applicant's argument that Stoltz deals with oil in water emulsions and does not exemplify use of the combination of n-butane and dimethylether propellant it is respectfully pointed out that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

**New rejections necessitated by claim amendments**

4. Claim **1, 5, 8-10 and 12-19** are rejected under 35 U.S.C. 103(a) as being unpatentable over WO0162211. ('211) (See Machine translation and translation attached and German patent DE 100 08 836A1 for translation purposes of WO 0162211, all presented in IDS and of record) in view of Stoltz (USP 5,824,289) and further in view of Reidel et al. (US PG pub. 2004/0197295 A1).

'211 discloses a propellant containing tooth cleaning agent, see title. The reference discloses tooth cleaning agents that contain polishing agents, humectants and tensides with celluloses that are filled in valve-operated dispenser filled with propellants, see abstract. The reference discloses stable dispersion which does not separate, see page 1, and paragraph 6. The amount of water is from 1-60 GEW by



percent, see page 1, and paragraph 8. Various propulsion gas mixtures are provided on page 2, paragraph 1 such as isopentane, neopentane and isobutene and mixture of C4 alkane and C5 alkane etc. (also see page 3 of German translation)

Polishing agents, finery bodies or abrasives which remove the tartar are disclosed on page 2, last paragraph. The polishing agents are finely divided with grain sizes and the amounts are disclosed to be between 5-50 GEW %. Suitable metaphosphates, calcium carbonates, and calcium phosphatase and various polishing agents are disclosed on page 2, 2-3 paragraph. Various silicas and silicates, alkali silicate and Zeodent are disclosed on page 2. Wet retaining means such as glycerol, propylene glycol and sorbitol are disclosed on page 2, section 5. Various surfactants are disclosed on page 2, section 6. The proportion of water in the composition is from, 1 to 60% by weight to 30 to 50% by weight and pH is from 5.5 to 9, see page 2 of translation. The preferred amount of propellant is from 3-4%, see under propellant gas in translation provided on page 2. On page 9 of translation the reference teaches binding agents and thickening agents. On page 4 of translation the mean particle size of polishing agents have been disclosed to be from 1 to 50 microns, 1 to 10 microns and from 1 to 200 microns and the amount of polishing agent is from 5 to 50% by weight. Humectants and surfactants are disclosed on page 6 of translation attached.

While the reference teaches utilizing propellants such as C4 alkane and isopentane etc., the reference does not specifically teach utilizing propellant mixture such as dimethylether and n-butane.

Stoltz teaches a foamable dental composition containing fluoride and aerosol propellant which provides stability to foam, see abstract and column 6, lines 61-67. The reference teaches utilizing well known propellants such as n-butane, propane and dimethylether with various psig vapor pressures. The reference also teaches chlorodifluoromethane propellants, see column 8, lines 45-50. The reference teaches in column 7, lines 32-37 that persons of ordinary skill would realize using other propellants in combination with the disclosed ones that is n-butane and isobutene. Example in column 7 teaches using dimethylether. The reference exemplifies using Dimethylether.

While the references discussed above suggest utilizing propellants, the references do not specifically disclose utilizing propellant mixture such as dimethylether and n-butane.

Riedel while teaching foamable preparations which can be dispensed from aerosol containers which are spray devices with a filling and propellants and such containers can be fitted with valves, teaches utilization of combination of known propellants such as dimethylether and butane, see title, see abstract, [0038], [[0042], [0043], [ 00051], [0053].

It would have been obvious to one of ordinary skill in the art at the time of instant invention to substitute the propellants such as n-butane and dimethylether in the primary reference in order to provide better dental foam stability motivated by the teachings of Stoltz et al. Since Reidel teaches utilization of combination of known propellants in aerosol formulation, it would have been obvious to one of ordinary skill in the art to have substituted the known combination of propellants such as n-butane and

dimethylether in the combined teachings of aerosol dentifrice preparation of WO and Stoltz with an expectation of obtaining predictable results that is stable aerosol formulation. Optimization of various amounts of various ingredients would have been within the purview of skilled artisan at the time of instant invention absent evidence to contrary.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-

272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612